

**A B S T R A C T**

The invention is directed to a clinical research data management system and method for a plurality of disparate users. The system includes a presentation creation mechanism operable to provide users with data from a database, an application control and navigation mechanism operable to service user requests and a data access mechanism operable to access information that resides in the database. The database is operable to store user data and study data. The study data includes candidate data, specimen data, event data and at least one dataset. The dataset is defined using metadata. The database is operable to store at least one roll associated with each user. User access to study data, candidate data, specimen data, event data and/or data sets is individually limited based on the at least one role associated with each user.

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